

CLAIMS

What is claimed is:

- 5 1. A particle-forming composition comprising a modafinil compound.
2. A composition of particles in an aqueous medium, wherein the
particles comprise a modafinil compound.
- 10 3. The composition of claims 1 or 2, wherein the modafinil compound is
modafinil.
4. The composition of claims 1 or 2, wherein the composition is
pharmaceutically acceptable.
- 15 5. The composition of claim 1, wherein the composition is non-aqueous.
6. The composition of claim 2, wherein the composition comprises a
stable suspension.
- 20 7. The composition of claims 1 or 2, further comprising at least one
surfactant.
8. The composition of claim 7, wherein the surfactant or surfactants
25 comprise from about 0.5% to about 50% (w/w) of the composition.
9. The composition of claim 8, wherein the surfactant or surfactants
comprise from about 1% to about 20% (w/w) of the composition.
- 30 10. The composition of claim 7, wherein the surfactant or surfactants is a
polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a saturated
polyglycolized glyceride, a fatty acid ester of polyethylene glycol, a medium chain

monoglyceride, a medium chain fatty acid ester, d- α -tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, or an ethoxylated hydroxystearic acid.

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11. The composition of claim 10, comprising a second surfactant.

12. The composition of claim 11, wherein the second surfactant is a polyoxyethylene sorbitan fatty acid ester.

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13. The composition of claim 12, wherein the second surfactant is sorbitan monolaurate or Polysorbate 80.

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14. The composition of claims 1 or 2, further comprising an organic solvent.

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15. The composition of claim 14, wherein the organic solvent is glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, a medium chain length monoglyceride, or a polyethyleneglycol.

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16. The composition of claim 15, further comprising benzyl alcohol, α -phenethyl alcohol or β -phenethyl alcohol.

17. The composition of claim 3, wherein modafinil is present at a concentration of about 1 to about 500 mg/ml.

18. The composition of claim 17, wherein modafinil is present at a concentration of about 1 to about 200 mg/ml.

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19. The composition of claims 1 or 2, wherein a modafinil compound is present at a concentration of about 1 to about 100 mg/ml; a first surfactant selected from a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a

saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, a medium chain monoglyceride, a medium chain fatty acid ester, d- α -tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, and an ethoxylated hydroxystearic acid; a second surfactant selected from a polyoxyethylene sorbitan fatty acid ester; and an organic solvent selected from glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, a medium chain length monoglyceride, or a polyethylene glycol.

20. The composition of claim 19, wherein the modafinil compound is modafinil.

21. The composition of claim 20, wherein the first surfactant is a saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, or a medium chain monoglyceride; the second surfactant is a polyoxyethylene sorbitan fatty acid ester; and the organic solvent is a polyethyleneglycol.

22. The composition of claim 21, wherein the first surfactant is glyceryl caprylate/caprate, glyceryl monocaprylate or polyethoxylated (40) stearic acid; the second surfactant is sorbitan monolaurate; and the organic solvent is PEG-300 or PEG-400.

23. The composition of claim 22, wherein the composition comprises 90% PEG-400, 5% sorbitan monolaurate, 5% glyceryl caprylate/caprate (w/w/w).

24. The composition of claim 22, wherein the composition comprises 90% PEG-400, 5% sorbitan monolaurate, 5% glyceryl monocaprylate (w/w/w).

25. The composition of claim 22, wherein the composition comprises 90% PEG-400, 5% sorbitan monolaurate, 5% polyethoxylated (40) stearic acid (w/w/w).

26. The composition of claim 21, wherein the first surfactant is glyceryl

caprylate/caprate, glyceryl monocaprylate, polyethoxylated (40) stearic acid or a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate; the second surfactant is polyoxyethylene (80) sorbitan monooleate; and the organic solvent is PEG-300 or PEG-400.

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27. The composition of claim 26, wherein the composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl caprylate/caprate (w/w/w).

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28. The composition of claim 26, wherein the composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl monocaprylate (w/w/w).

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29. The composition of claim 26, wherein the composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% polyethoxylated (40) stearic acid (w/w/w).

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30. The composition of claim 26, wherein the composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% of a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate (w/w/w).

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31. The composition of claim 10, wherein the composition comprises Polysorbate 80, glyceryl caprylate/caprate and a mixture of glyceryl tricaproate and glyceryl tricaprilate.

32. The composition of claims 1 or 2, comprising one or more unit doses of a modafinil compound.

33. The composition of claim 32, comprising one unit dose of a modafinil compound.

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34. The composition of claim 33, wherein the unit dose is 200 mg.

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35. The composition of claim 33, wherein the unit dose is 100 mg.

36. A method of preparing a composition of particles, wherein the particles
5 comprise a modafinil compound, comprising contacting a particle-forming
composition of modafinil with an aqueous medium.

37. The method of claim 36, wherein the particle-forming composition is
10 contacted with an aqueous medium in vitro.

38. The method of claim 36, wherein the particle-forming composition is
contacted with an aqueous medium in vivo.

39. The method of claim 36, wherein the modafinil compound is
15 modafinil.

40. A method of preparing a composition of particles, wherein the particles
comprise a modafinil compound, comprising:

(a) dissolving a modafinil compound in a liquid comprising at least one
20 surfactant in an amount from about 1% to about 50%, to form a particle-forming
composition; and

(b) contacting the particle-forming composition with an aqueous medium
to form the composition of particles.

41. A method of treating a disease or disorder in a subject, comprising
25 administering a therapeutically effective amount of a modafinil compound in a
particle-forming composition comprising at least one surfactant to a subject.

42. A method of treating a disease or disorder in a subject, comprising:

(a) contacting a modafinil compound in a particle-forming composition
30 comprising at least one surfactant with an aqueous medium, thereby forming a
composition of particles, wherein the particles comprise a modafinil compound; and

(b) administering a therapeutically effective amount of the composition of particles to a subject.

5 43. The method of claims 40, 41 or 42, wherein the modafinil compound is modafinil.

10 44. The method of claim 41 or 42, wherein the composition is administered for the treatment of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive dysfunction or fatigue; and for the promotion of wakefulness, stimulation of appetite, or stimulation of weight gain to a patient in need thereof.

15 45. The composition of claim 3, wherein upon administration of the composition to a subject in need thereof, modafinil has a blood serum level of about 0.05 to about 30 µg/ml in said subject.

46. The composition of claim 45, wherein the blood serum level is from about 1 to about 20 µg/ml.

20 47. The composition of claim 1, wherein the composition is suitable for oral administration to a subject.

25 48. The composition of claim 47, wherein the composition is encapsulated within a capsule.

49. The composition of claim 48, wherein the capsule is a soft gelatin capsule.

30 50. The composition of claim 48, wherein the capsule is a hard capsule.

51. The composition of claim 2, wherein the composition is suitable for oral administration to a subject.

52. The composition of claim 51, wherein the composition is encapsulated within a capsule.

53. The composition of claim 52, wherein the capsule is a hard capsule.

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54. The composition of claim 51, wherein the composition is a syrup, elixir, or emulsion.

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